John C. Fowler (SBN 235376)
FOWLER | HELSEL | VOGT
67 Main Street
Sutter Creek, CA 95685
Tel.: (209) 267-8181
Fax: (209) 560-6137
E-mail: john@fhvlaw.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

MARY MOORE, an individual, Plaintiff, vs. PHILIPS NORTH AMERICA LLC; PHILIPS RS NORTH AMERICA LLC; KONINKLIJKE PHILIPS N.V.; and DOES 1 through 10; Defendants.	Case No.: **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL FOR:** 1. Negligence 2. Products Liability: Design Defect 3. Products Liability: Manufacturing; 4. Product Liability: Failure to Warn; 5. Breach of Express Warranty; 6. Breach of Implied Warranty of Merchantability; 7. Fraudulent Misrepresentation; 8. Fraud by Omission; and 9. Negligent Misrepresentation.

Plaintiff MARY MOORE ("Plaintiff"), hereby complains and alleges against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips N.A."), and Philips RS North America LLC ("Philips RS"), and DOES 1 through 10, based on (A) personal knowledge, (b) the investigation of counsel, and (c) information and belief, as follows:

///

///

///

I.

INTRODUCTION

1. Plaintiff brings this action for injuries caused by the use of the Trillium 100 device designed, manufactured, and/or sold, by Defendants, and each of them, which contain polyester based polyurethane sound abatement foam ("PE-PUR Foam").

2. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had determined that: (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation. Philips further disclosed in its Recall Notice that, "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."

4. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").

5. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devices (extending from the device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection from users of these devices.

6. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam in these

devices include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

7. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

8. In or around May 2017, Plaintiff MARY MOORE purchased a Philips Trilogy 100 Ventilator device, which she used regularly from the date of purchase until she received Philips recall notice in or about June 2021.

9. After she began using the Philips Trilogy 100 Ventilator, Plaintiff began to experience chronic sinusitis and was diagnosed with chronic sinusitis and squamous cell carcinoma, requiring multiple surgical interventions. Plaintiff has also partially lost vision in her right eye as a result of the carcinoma and must undergo chemotherapy.

10. Further, Plaintiff has been prescribed medications and anticipates needing significant, continuing medical care and treatment into the foreseeable future.

11. Plaintiff has incurred substantial expenses for medical care and is unable to continue to use the Trilogy 100 device due to continuing concerns for her health and wellbeing. In addition, Plaintiff has and continues to experience congestion, runny nose, nasal discomfort, dry mouth, and constant sore throat during use of the Philips' recalled machine. Since being notified of the recall, Plaintiff has experienced anxiety concerning the health risks she is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the Recalled machines, including the machine used by Plaintiff.

12. Plaintiff seeks to recover damages based on, inter alia, Defendants' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing and sales of devices containing PE-PUR Foam.

II.

PARTIES

13. Plaintiff MARY MOORE is a citizen of the State of California.

14. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS. Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.

15. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

16. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

17. Defendants Royal Philips, Philips NA, and Philips RS are collectively referred to herein as "Philips" or "Defendants."

III.

JURISDICTION AND VENUE

18. Jurisdiction of this Court is based on Diversity of Citizenship and the amount in controversy is well in excess of the jurisdictional limit of $75,000.00. 28 U.S.C. § 1332(a)(1)-(3).

19. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because Defendants transact business in this District, a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District and Plaintiff resides in this District.

20. The Court has personal jurisdiction over Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiff's claims arise out of and relate to Defendants' contacts with this District. Defendants Philips RS and Philips NA are controlled by their parent Royal Philips. Defendants' affiliations with this District are so

continuous and systematic as to render them essentially at home in the forum State. Further, Defendants have transacted business, maintained substantial contacts, purposefully targeted consumers and medical professionals for sales of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States. The unlawful acts of Defendants have been directed at, targeted, and have had the effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

IV.

FACTUAL BACKGROUND

A. Continuous Positive Airway Pressure Therapy

21. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

22. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure Therapy.

23. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical

and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

C. Mechanical Ventilation

24. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

V.

SUBSTANTIVE ALLEGATIONS

25. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP respiratory devices and mechanical ventilators under its "Sleep & Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP respirator devices and its mechanical ventilators typically cost several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

///

///

A. Philips Sleep & Respiratory Care Devices Endangered Users

26. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."

27. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices." Specifically, Philips announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.

28. The list of the devices recalled by Philips (the "Recalled Devices" or "Recalled Machines") include:

Philips CPAP and Bi-Level PAP Devices

Manufactured Before April 26, 2021 Subject to Recall

Device Name/Model Type

- E30 (Emergency Use Authorization) – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV; C Series S/T and AVAPS; OmniLab Advanced Plus – Continuous Ventilator, Non-life Supporting
- SystemOne (Q Series); DreamStation; DreamStation GO; Dorma 400; Dorma500; REMStar SE Auto – Non-continuous Ventilator

Philips Mechanical Respirator Devices

Manufactured Before April 26, 2021 Subject to Recall

Device Name/Model Type

- **Trilogy 100 Ventilator**; Trilogy 200 Ventilator; Garbin Plus, Aeris, LifeVentVentilator – Continuous Ventilator;
- A-Series BiPAP Hybrid A30; Philips A-Series BiPAP V30 Auto – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- Philips A-Series BiPAP A40; Philips A-Series BiPAP A30 – Continuous Ventilator, Non-life Supporting

29. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects."

30. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."

31. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."

32. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."

B. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless

33. As a result of the health risks associated with the use of the Recalled Devices, together with Defendants' concealment of these risks from the date they were first reported to Defendants or discovered by Defendants through April 26, 2021, the Recalled Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

34. The information described above, including the now-known health risks of Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea and respiratory conditions. Individuals not using life-supporting ventilators must immediately discontinue their user of the Recalled Devices or face serious health risks as grave as organ failure or cancer. If they choose to discontinue use of the Recalled Devices, they must pay for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Device.

35. Recognizing this, Philips issued the following advice to patients using any of the Recalled Devices:

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."

36. As a result of the above, Plaintiff will have to undertake considerable expense replacing the Recalled Device.

C. Philips Unreasonably Delayed its Recall

37. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas or degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Devices.

38. Defendants have not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

///

39. At a minimum, as a result of user reports, Defendants were aware of the off-gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall yet continued to manufacture and sell the Recalled Devices with such awareness. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

D. Plaintiff MARY MOORE

40. Plaintiff MARY MOORE is a resident and citizen of Tulare County, California.

41. Plaintiff purchased a Recalled Device, a Trilogy 100 Ventilator device, prior to June 14, 2021.

42. The manuals accompanying Plaintiff's device did not contain any language or warnings of health risks associated with use of the device, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects. Had Defendants informed Plaintiff of these risks, she would not have purchased or used the Recalled Device.

43. Without knowing of the health risks associated with use of the Recalled Device, Plaintiff used the Recalled Device regularly to treat her low oxygen condition until learning on or about June 26, 2021 that the devices were recalled.

44. As a result of the health risks associated with continued use of the Recalled Device, Plaintiff was diagnosed with serious physical injuries including without limitation chronic sinusitis, nasal congestion, chronic pain sinusitis, inverted papilloma, neoplastic right nasal polyp, and squamous cell carcinoma.

VI.

TOLLING AND ESTOPPEL

A. Discovery Rule Tolling

45. Plaintiff had no way of knowing about Defendants' conduct with respect to the health risks associated with the use of the Recalled Device.

///

46. Plaintiff, through the exercise of reasonable care, could not have discovered the conduct by Defendants alleged herein. Further, Plaintiff did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

47. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiff.

B. Fraudulent Concealment Tolling

48. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Device, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff.

49. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff. Plaintiff was unaware of the facts alleged herein without any fault or lack of diligence on her part and could not have reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

VII.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

NEGLIGENCE

50. Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including the Recalled Devices.

51. Defendants were negligent in failing to use reasonable care as described herein in designing and manufacturing, the recalled machines, as well as the machine that Plaintiff purchased and used. Defendants breached their aforementioned duty by:

a. Failing to design the recalled machines so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;

///

b. Including in the design of the recalled machines flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

c. Manufacturing certain Philips machines, including the recalled machines, with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

d. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Recalled Devices.

52. Defendants also negligently failed to warn or instruct the Plaintiff in the following manners:

a. the recalled machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

b. the recalled machine's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;

c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

d. the risk of chronic inflammation resulting from use of the recalled machines;

e. the risk of chronic infections resulting from the recalled machines;

f. the risk of lung, kidney, and/or rectal cancers from exposure to the foam;

g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines;

///

h. the severity of complications that could arise as a result of implantation of the recalled machines;

53. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

54. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SECOND CAUSE OF ACTION

PRODUCT LIABILITY: DESIGN DEFECT

55. The recalled machine used by Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to its design. As previously stated, the machine's design defects include, but are not limited to:

a. the use of polyurethane PE-PUR sound abatement foam in the recalled machines and the immune reaction that results from such material, causing adverse reactions and injuries;

b. Failing to design the recalled machines so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;

c. Including in the design of the recalled machines flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer as well as other injuries;

///

///

///

d. Failing to use alternatively available sound abatement materials and/or foams in the recalled machines, such as plastic, silicone, or rubber, which would not break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the recalled machines.

56. At all times, the use of the recalled machines, as well as Plaintiff's use of the Recalled Device (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff in the manner intended by Defendants.

57. The recalled machine used by Plaintiff, was defective in their design in that it failed to perform as safely as a reasonable consumer would expect when used in an intended or reasonably foreseeable manner.

58. The recalled machines, including the Recalled Device used by Plaintiff, are further defective in that the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger posed by the design was great, the likelihood that such danger would cause injury was substantial, there were feasible, safer alternative designs known to Defendants at the time of manufacture, the financial costs of an improved design was minor and there were likely no adverse consequences to the product, or to the user, that would result from an alternative design.

59. Defendants, and each of them, knew that the recalled machines, including the Plaintiff's Recalled Device, and the component parts of these CPAP/BIPAP machines would be purchased and used without inspection for defects in the design of the machine or its masks/attachments.

60. The recalled machines, including the Plaintiff's Recalled Device, and the component parts of these machines were defective when they left the control of each of these Defendants.

61. As a direct and proximate result of the recalled machines, including Plaintiff's Recalled Device, and the aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone

medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

62. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including Plaintiff's Recalled Device.

63. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

64. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

THIRD CAUSE OF ACTION

PRODUCT LIABILITY: MANUACTURING DEFECT

65. At all times, the use of the recalled machines, as well as Plaintiff's use of the Recalled Device (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by Plaintiff in the manner intended by Defendants.

66. The recalled machines were defective at the time of their manufacture, development, production, testing, inspection, endorsement, sale and distribution, and at the time they left the possession of the Defendants, in that, and not by way of limitation, the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

67. Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, including (among other things), that the PE-PUR foam used in the recalled machine's component parts was prone to flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

68. The Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, and the component parts of these CPAP/BIPAP machines, including among other things, that the PE-PUR foam used in the recalled machine's component parts was prone to flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

69. Specifically, the Defendants improperly designed the recalled machines by manufacturing certain Philips machines, including the recalled machines, with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including cancer, as well as other injuries.

70. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

71. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION

PRODUCT LIABILITY: FAILURE TO WARN

72. The recalled machines, including the Recalled Device used by Plaintiff, were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings including, but not limited to, the following:

a. the recalled machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including cancer, as well as other injuries;

b. the recalled machine's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;

c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;

d. the risk of chronic inflammation resulting from use of the recalled machines;

e. the risk of chronic infections resulting from the recalled machines;

f. the risk of lung, kidney, and/or rectal cancers from exposure to the foam;

g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines;

h. the severity of complications that could arise as a result of implantation of the recalled machines;

73. As a direct and proximate result of the recalled machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

74. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective device.

75. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

///

///

///

///

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

76. Philips marketed and sold the Recalled Device into the stream of commerce with the intent that the Recalled Device would be purchased by Plaintiff and other members of the general public.

77. Philips expressly warranted, advertised, and represented to Plaintiff that the Recalled Device was safe and appropriate for human use.

78. Philips made these express warranties regarding the Recalled Device's quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Device's packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff entered into upon purchasing the Recalled Device.

79. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Device, were made in connection with the sale of the Recalled Device to Plaintiff. Plaintiff relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Device in deciding whether to purchase and use Philips' Recalled Device.

80. The recalled machines, including the Recalled Device used by Plaintiff, did not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

81. Philips therefore breached its express warranties by placing the recalled machines, including the machine used by Plaintiff, into the stream of commerce and selling it to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, and safety of the Recalled machines, and rendered the machines worthless.

82. Philips was aware, or should have been aware, of the toxic or dangerous health effects from the use of the recalled machines, including the machine used by Plaintiff, but nowhere

on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiff she was at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the recalled machines

83. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the recalled machines, including the machine used by Plaintiff and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

84. The adverse health effects associated with use of the recalled machines, including the machine used by Plaintiff existed when they left Philips' possession or control and were sold to Plaintiff. The dangers associated with use of the recalled machines were undiscoverable by Plaintiff at the time of purchase of the Recalled Device.

85. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

86. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions to induce Plaintiff to rely on such representations and omissions.

87. Philips' affirmations of fact and promises and its omissions were material, and Plaintiff reasonably relied upon such representations and omissions in purchasing and using the Recalled Device.

88. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiff.

89. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices, including the machine used by Plaintiff was unsafe. Philips had ample opportunity either to stop using the PEPUR Foam or to replace the PE-PUR Foam in the Recalled Devices to make them safe and healthy for use by Plaintiff but failed to do so until now.

90. As a direct and proximate result of the recalled machines, including the machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

91. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

92. Philips are merchants engaging in the sale of goods to Plaintiff and members of the general public.

93. There was a direct sale of goods from Philips to Plaintiff, creating privity between Plaintiff and Defendants.

94. At all times mentioned herein, Philips manufactured or supplied the recalled machines, including the machine used by Plaintiff, and prior to the time of use, Philips impliedly warranted to Plaintiff that the Recalled Devices, including the machine used by Plaintiff was of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on the labels and packaging, including that the machines were safe and appropriate for human use. Plaintiff relied on Philips' promises and affirmations of fact and omissions when she purchased and used the Recalled Device.

95. Contrary to these representations and warranties, the Recalled Devices, including the machine used by Plaintiff was not fit for its ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

96. Philips breached its implied warranties by selling a Recalled Device, including the machine used by Plaintiff that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Device was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

97. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through user reports submitted to Philips and through lab testing.

98. Privity exists because Philips impliedly warranted to Plaintiff through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices.

99. As a direct and proximate result of the Recalled Devices, including the aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

100. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SEVENTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

101. Philips failed to advise Plaintiff that the Recalled Devices, including the machine used by Plaintiff posed serious health risks to their users and Philips falsely represented to Plaintiff that the Recalled Devices were safe for human use.

///

///

102. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and other members of the general public to purchase the Recalled Devices, including the machine used by Plaintiff.

103. Philips knew that its representations and omissions about the Recalled Devices, including the machine used by Plaintiff, were false in that the Recalled Devices contained PE-PUR Foam and thus were at risk of causing adverse health effects to users of the Recalled Devices which does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff.

104. Plaintiff did in fact rely on these omissions and misrepresentations and purchased and used a Recalled Device to her detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, Plaintiff's reliance on Philips' omissions and misrepresentations was justifiable.

105. As a direct and proximate result of the recalled machines, including the machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

106. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

EIGHTH CAUSE OF ACTION

FRAUD BY OMISSION

107. Philips concealed from and failed to disclose to Plaintiff that use of Recalled Devices, including the machine used by Plaintiff is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

108. Philips was under a duty to disclose to Plaintiff the true quality, characteristics, ingredients and suitability of the Recalled Devices, including the machine used by Plaintiff because:

a. Philips was in a superior position to know the true state of facts about its products;

b. Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled Devices; and

c. Philips knew that Plaintiff could not reasonably have been expected to learn or discover prior to purchasing the Recalled Device that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

109. The facts concealed or not disclosed by Philips to Plaintiff were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled Device.

110. Plaintiff justifiably relied on Philips' omissions to her detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled Devices, including the machine used by Plaintiff, which is inferior when compared to how the Recalled Devices are advertised and represented by Philips.

111. As a direct and proximate result of the Recalled Devices, including the machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

112. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

///

NINTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

113. Philips had a duty to Plaintiff to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices, including the machine used by Plaintiff.

114. Philips breached its duty to Plaintiff by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled Devices, including the machine used by Plaintiff from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

115. Philips knew or should have known that the qualities and characteristics of the Recalled Devices, including the machine used by Plaintiff were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips knew or should have known that:

a. the use of the Recalled Devices was accompanied by risks of adverse health effects that do not conform to the packaging and labeling;

b. the Recalled Devices were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and

c. the Recalled Devices were otherwise not as warranted and represented by Philips.

116. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

117. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VIII.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, as follows.

a. For past and future general damages on each cause of action, according to proof;

b. For past and future pain and suffering, according to proof;

c. For past and future hospital, medical, nursing care, treatment and incidental expenses, according to proof;

d. For past and future loss of earnings and earning power, according to proof;

e. For past and future mental and emotional distress, according to proof;

f. For restitution, according to proof;

g. For punitive damages in an amount appropriate to punish and/or set an example of Defendants, or in any other way appropriate;

h. For past and future costs of suit incurred herein, and attorney's fees as may be allowed by law; and

i. For such other and further relief as the Court may deem just and proper.

Dated: December 23, 2022 FOWLER | HELSEL | VOGT

John C. Fowler, Esq.
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury for all issues so triable.

Dated: December 23, 2022 FOWLER | HELSEL | VOGT

John C. Fowler, Esq.
Attorneys for Plaintiff